

REMARKS

Reconsideration of this application, as amended, is respectfully requested.

In the Office Action, claims were rejected as anticipated by Leins, Abouaf, and Hood. Claims were also rejected as allegedly obvious over the combination of Leins in view of Abouaf.

The presently pending independent claims recite that the surgical or medical instrument or tool does not form iron particles during use. It is respectfully submitted that none of the cited references teach or suggest this feature.

The core theme of the present invention is the use of biocompatible, bioinert material for the manufacture of medical/surgical instruments which are to be employed in order to avoid detrition particles caused by the operation and having an osteolytic action. With the medical/surgical instruments and tools of the present invention, the (Fe) detrition particles producing osteolytic [bone-destroying] effects are avoided.

As set forth in the description, very early studies on patients with implants and prostheses showed that, in the periprosthetic tissue traces of iron could be detected. This finding was surprising in that iron could be detected even when implants and prostheses made of absolutely iron-free materials had been used, and the explanation of the implants and prostheses and the analysis of the periprosthetic tissue had been performed with iron-free research instruments. Even in the case of explantations made of absolutely iron-free materials, for example even in the case of titanium prostheses, iron up to 1 mg/g of tissue was detected in the periprosthetic tissue by such tests.

It was only on the basis of results obtained by a special test methodology that the inventors were able to draw the conclusion that the iron detected in periprosthetic tissue of iron-free implants and prostheses must have been introduced during the operation. Only with this discovery could the problem on which the present invention was based be formulated, namely, to prepare tools and instruments which during operations, for

example, in bone surgery during the insertion of implants, would cause no detrition of iron, in order thereby to prevent osteolytically acting iron in the tissue.

Turning to the cited references, with respect to Leins, the Examiner argues that one could use the drill bit as a surgical instrument, but nowhere is there motivation to do so, since Leins teaches that the drill bit has a structure that provides a good discharge of the shavings (col. 2, lines 16-18. The Background discusses drilling with high speed steel and hard metal tools, but nowhere is it suggested to use such a tool in medical or surgical use. Furthermore, biocompatibility and bioinert qualities of the materials used to make the instruments or tools are not discussed.

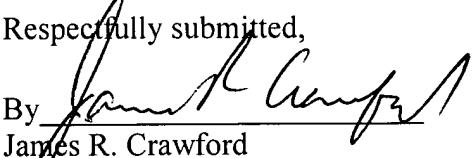
The Examiner is reminded that to rely on a reference as the basis for a 102/103 rejection on inherency, the Examiner must show that the certain result or characteristic necessarily flows from the teachings of the prior art. See *in re Rijckaert*, 28 USPQ2d, 1955, 1957 (Fed. Cir. 1993); *In re Oelrich*, 212 USPQ 323 (CCPA 1981) *Ex parte Levy*, 17 USPQ2d 1464 (Bd. Pt. App. & Inter 1990) and MPEP §2112.

In view of the forgoing, allowance is respectfully requested.

The Commissioner is hereby authorized to charge any deficiency in the fees filed, asserted to be filed or which should have been filed herewith (or with any paper hereafter filed in this application by this firm) to our Deposit Account No. 50-0624, under Order No. NY-CERA 233-US.

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Respectfully submitted,

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